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EXAMINER	
DOWELL, PAUL THOMAS	
ART UNIT	**PAPER NUMBER**
1632	

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/511,627	EULENBERG ET AL.	
	Examiner	Art Unit	
	Paul Dowell	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-33 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-33 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claims 1-33 are pending.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I(i), claims 1-7, 10-14, 18-19, 31, drawn to a pharmaceutical composition comprising an CG7956 **nucleic acid molecule**; a host cell comprising an CG7956 nucleic acid molecule; and a method of using said nucleic acid molecule for controlling the function of a gene.

Group I(ii), claims 1-7, 10-13, 18-19, 31, drawn to a pharmaceutical composition comprising an aralar1 **nucleic acid molecule** and a host cell comprising an aralar1 nucleic acid molecule.

Group I(iii), claims 1-7, 10-13, 18-19, 31, drawn to a pharmaceutical composition comprising an how **nucleic acid molecule** and a host cell comprising an how nucleic acid molecule.

Group I(iv), claims 1-7, 10-13, 18-19, 31, drawn to a pharmaceutical composition comprising an CG9373 **nucleic acid molecule** and a host cell comprising an CG9373 nucleic acid molecule.

Group I(v), claims 1-7, 10-13, 18-19, 31, drawn to a pharmaceutical composition comprising an cpo **nucleic acid molecule** and a host cell comprising an cpo nucleic acid molecule.

Group I(vi), claims 1-7, 10-13, 18-19, 31, drawn to a pharmaceutical composition comprising an Jafrac1 **nucleic acid molecule** and a host cell comprising an Jafrac1 nucleic acid molecule.

Group I(vii), claims 1-7, 10-13, 18-19, 31, drawn to a pharmaceutical composition comprising a CG14440 **nucleic acid molecule** and a host cell comprising an CG14440 nucleic acid molecule.

Group I(viii), claims 1, 8, 9, 11-13 and 31, drawn to a pharmaceutical composition comprising a **polypeptide** encoded by a CG7956 nucleic acid molecule.

Group I(ix), claims 1, 8, 9, 11-13 and 31, drawn to a pharmaceutical composition comprising a **polypeptide** encoded by a aralar 1 nucleic acid molecule.

Group I(x), claims 1, 8, 9, 11-13 and 31, drawn to a pharmaceutical composition comprising a **polypeptide** encoded by a how nucleic acid molecule.

Group I(xi), claims 1, 8, 9, 11-13 and 31, drawn to a pharmaceutical composition comprising a **polypeptide** encoded by a CG9373 nucleic acid molecule.

Group I(xii), claims 1, 8, 9, 11-13 and 31, drawn to a pharmaceutical composition comprising a **polypeptide** encoded by a cpo nucleic acid molecule.

Group I(xiii), claims 1, 8, 9, 11-13 and 31, drawn to a pharmaceutical composition comprising a **polypeptide** encoded by a Jafrac 1 nucleic acid molecule.

Group I(xiv), claims 1, 8, 9, 11-13 and 31, drawn to a pharmaceutical composition comprising a **polypeptide** encoded by a CG14440 nucleic acid molecule.

Group II, claim 1, 31, drawn to a pharmaceutical composition comprising **an effector/modulator** that is not a nucleic acid or a polypeptide.

Group III(i), claim 14, drawn to a method of using an **effector/modulator** for controlling the function of a gene.

Group III(ii), claim 14, drawn to a method of using an aralar1 **nucleic acid** for controlling the function of a gene.

Group III(iii), claim 14, drawn to a method of using an how **nucleic acid** for controlling the function of a gene.

Group III(iv), claim 14, drawn to a method of using an CG9373 **nucleic acid** for controlling the function of a gene.

Group III(v), claim 14, drawn to a method of using an cpo **nucleic acid** for controlling the function of a gene.

Group III(vi), claim 14, drawn to a method of using an Jafrac1 **nucleic acid** for controlling the function of a gene.

Group III(vii), claim 14, drawn to a method of using an CG14440 **nucleic acid** for controlling the function of a gene.

Group III(viii), claim 14, drawn to a method of using a **polypeptide** encoded by a aralar1 nucleic acid for controlling the function of a gene.

Group III(ix), claim 14, drawn to a method of using a **polypeptide** encoded by a how nucleic acid for controlling the function of a gene.

Group III(x), claim 14, drawn to a method of using a **polypeptide** encoded by a CG9373 nucleic acid for controlling the function of a gene.

Group III(xi), claim 14, drawn to a method of using a **polypeptide** encoded by a cpo nucleic acid for controlling the function of a gene.

Group III(xii), claim 14, drawn to a method of using a **polypeptide** encoded by a Jafrac1 nucleic acid for controlling the function of a gene.

Group III(xiii), claim 14, drawn to a method of using a **polypeptide** encoded by a CG14440 nucleic acid for controlling the function of a gene.

Group IV(i), claim 15, drawn to a method of using **an effector/modulator** for identifying substances capable of interacting with polypeptides.

Group IV(ii), claim 15, drawn to a method of using an CG7956 **nucleic acid** molecule for identifying substances capable of interacting with polypeptides.

Group IV(iii), claim 15, drawn to a method of using an aralar1 **nucleic acid** molecule for identifying substances capable of interacting with polypeptides.

Group IV(iv), claim 15, drawn to a method of using an how **nucleic acid** molecule for identifying substances capable of interacting with polypeptides.

Group IV(v), claim 15, drawn to a method of using an CG9373 **nucleic acid** molecule for identifying substances capable of interacting with polypeptides.

Group IV(vi), claim 15, drawn to a method of using an cpo **nucleic acid** molecule for identifying substances capable of interacting with polypeptides.

Group IV(vii), claim 15, drawn to a method of using an Jafrac1 **nucleic acid** molecule for identifying substances capable of interacting with polypeptides.

Group IV(viii), claim 15, drawn to a method of using an CG14440 **nucleic acid** molecule for identifying substances capable of interacting with polypeptides.

Group IV(ix), claim 15, drawn to a method of using a **polypeptide** encoded by a CG7956 nucleic acid molecule for identifying substances capable of interacting with polypeptides.

Group IV(x), claim 15, drawn to a method of using a **polypeptide** encoded by a aralar 1 nucleic acid molecule for identifying substances capable of interacting with polypeptides.

Group IV(xi), claim 15, drawn to a method of using a **polypeptide** encoded by a how nucleic acid molecule for identifying substances capable of interacting with polypeptides.

Group IV(xii), claim 15, drawn to a method of using a **polypeptide** encoded by a CG9373 nucleic acid molecule for identifying substances capable of interacting with polypeptides.

Group IV(xiii), claim 15, drawn to a method of using a **polypeptide** encoded by a cpo nucleic acid molecule for identifying substances capable of interacting with polypeptides.

Group IV(xiv), claim 15, drawn to a method of using a **polypeptide** encoded by a Jafrac 1 nucleic acid molecule for identifying substances capable of interacting with polypeptides.

Group IV(xv), claim 15, drawn to a method of using a **polypeptide** encoded by a CG14440 nucleic acid molecule for identifying substances capable of interacting with polypeptides.

Group V(i), claims 16-17 drawn to a non-human transgenic animal exhibiting a modified expression of an CG7956 polypeptide.

Group V(ii), claims 16-17 drawn to a non-human transgenic animal exhibiting a modified expression of an aralar1 polypeptide.

Group V(iii), claims 16-17 drawn to a non-human transgenic animal exhibiting a modified expression of an how polypeptide.

Group V(iv), claims 16-17 drawn to a non-human transgenic animal exhibiting a modified expression of an CG9373 polypeptide.

Group V(v), claims 16-17 drawn to a non-human transgenic animal exhibiting a modified expression of an cpo polypeptide.

Group V(vi), claims 16-17 drawn to a non-human transgenic animal exhibiting a modified expression of an Jafrac1 polypeptide.

Group V(vii), claims 16-17 drawn to a non-human transgenic animal exhibiting a modified expression of an CG14440 polypeptide.

Group VI(i), claim 20, drawn to a method of identifying a polypeptide involved in the regulation of energy homeostasis.

Group VI(ii), claim 20, drawn to a method of identifying a polypeptide involved in the metabolism of triglycerides.

Group VII, claim 21, drawn to a method of screening for an agent that modulates the interaction of a polypeptide with a target.

Group VIII, claim 22, drawn to a method of screening for an agent that modulates the activity of a polypeptide.

Group IX, claims 23-24, 32, drawn to a method of making a pharmaceutical polypeptide composition.

Group X(i), claim 25, 27, 33, drawn to a method of using a pharmaceutical polypeptide composition as a prophylactic for a disease.

Group X(ii), claim 25, 27, 33, drawn to a method of using a pharmaceutical polypeptide composition as a treatment for a disease.

Group XI, claim 30, drawn to a method of using a nucleic acid molecule for the production of a non-human animal.

Group XII(i), claim 26, 28, drawn to a method of using a pharmaceutical nucleic acid composition as a prophylactic for a disease.

Group XII(ii), claim 26, 28, drawn to a method of using a pharmaceutical nucleic acid composition as a treatment for a disease.

Group XII(iii), claim 29, drawn to a method of using a pharmaceutical host cell composition as a prophylactic for a disease.

Group XII(iv), claim 29, drawn to a method of using a pharmaceutical host cell composition as a treatment for a disease.

The inventions listed as groups I-XII do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

37 CFR 1.475 (c) states:

"If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475 (d) states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each of the other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and §1.476(c)."

37 CFR 1.475 (e) states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim."

In view of 37 CFR 1.475 (e), Groups I and II are considered a plurality of the inventions listed in claim 1, for example.

In view of 37 CFR 1.475 (c) and 37 CFR 1.475 (d), group I is considered the main invention that is drawn to the first product, first mentioned in the claims of the

application (i.e. a composition comprising CG7956 nucleic acid) and the first recited invention drawn to other categories related thereto (i.e. a method of using said composition).

The instant claims encompass a plurality of distinct inventions exemplified by structurally distinct nucleic acid sequences that encode structurally and functionally distinct polypeptides. Because the nucleic acids have no shared structural sequences, said nucleic acids lack unity of invention. ***Upon election of any one of groups I-XII, Applicants are required to choose a specific vertebrate or insect nucleic acid and corresponding polypeptide.*** This is not a species election. While nucleic acids and their correspondingly encoded polypeptides are also structurally distinct, under the rules for unity of invention, they are examined together. However, said rule does not apply to distinct gene sequences or distinct polypeptides encoded by separate genes.

Groups I(ii)-XII are drawn to distinct processes of use and distinct products that do not share the same inventive concept as in group I(i). The inventions of groups I(ii)-XII are drawn to distinct materials and/or method steps that are neither required nor recited in the invention of group I(i), and thus have their own technical features, e.g. a therapeutic composition comprising an aralar 1 nucleic acid (group I(ii)), a therapeutic composition comprising a polypeptide encoded by an aralar 1 nucleic acid (group I(ix)), an effector that is not a nucleic acid (group II), control of gene function (group III), a method for identifying substances using an effector/modulator (group IV(i)) or using various nucleic acids (groups IV(ii)-IV(Viii)), a transgenic animal (group V), a method of

identifying polypeptides (group VI), methods of screening for agents that modulate interaction or activity of polypeptide (groups VII and VIII), a method of making a pharmaceutical polypeptide (group IX), methods of using a polypeptide as prophylactic or treatment (group X), a method of making a transgenic animal (group XI), methods of using a nucleic acid as prophylactic or treatment (groups XII(i) and XII(ii)) and methods of using a host cell as prophylactic or treatment (groups XII(iii) and XII(iv)). Further, each of the groups has a technical feature not required for the other groups.

For example, the compositions of groups I(i)-I(vii) comprise nucleic acids, whereas the compositions of group I(viii)-I(xiv) comprise polypeptides, whereas the composition of group II comprises effector/modulator molecules that do not comprise a nucleic acid or a polypeptide and are therefore structurally distinct. The method of group III is distinct from the method of group I for which nucleic acids are utilized that are not required for the method of group III. The methods of group IV are directed to the identification of substances, whereas the methods used in group I are directed to control of gene function. Therefore the inventions of groups I and groups IV are distinct. In addition, the effector/modulator of group IV(i) is not required for the nucleic acid of groups IV(ii-xi) and *vice versa*. The non-human transgenic animals of groups V are structurally and physiologically distinct from the pharmaceutical compositions of groups I. The methods of groups VI(i) and VI(ii) are each distinct from the other, because one involves the regulation of energy homeostasis, whereas the other is relevant to the metabolism of triglycerides. Hence, the methods of groups VI are also distinct from that of group I. The methods of groups VII and VIII are directed to screening for agents that

respectively modulate interaction and activity to a polypeptide and are therefore each distinct from the methods involving gene control of groups I. The method of group IX is directed to a method of making a pharmaceutical composition that is not required for any of the inventions in groups I-VIII. The inventions of groups X(i), XII(i), XII(iii) are distinct each from the inventions of groups X(ii), XII(ii), XII(iv) because prophylactic (i.e. preventative before disease onset) and therapeutic (i.e. treatment after disease onset) applications are directed to separate goals. Further the nucleic acid molecules of group I are not required for the methods of outlined in inventions of groups X(i) and X(ii), therefore each are distinct. The method of group XI is directed to the making of a transgenic animal and therefore constitutes a separate category of invention than the composition of groups I. Further, in the instant case, the search and examination of the compositions and methods of making and using described in inventions of groups I-XII for prior art and patentability are not coextensive.

Each invention is directed to a distinct goal, which comprises the use of separate products or methods in order to achieve its respective and intended objective. Thus, it follows from the preceding analysis that the claimed inventions listed as groups I to XII do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features for the reasons set forth above.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

A specifically named disease or disorder as recited in claim 13, 14, 24-29 and 33.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 13, 14, 24-29 and 33, and claims dependent therefrom correspond to all the species listed above.

The following claim(s) are generic: 13, 14, 24-29 and 33.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or

corresponding special technical features for the following reasons: As the technical features (as for example: metabolic diseases, hypertension, osteoarthritis, gallstones and other diseases or disorders) linking the members do not constitute a special technical feature as defined by PCT Rule 13.2, particularly since each of the species does not share a substantially common structural feature or function, the requirement for unity of invention is not fulfilled.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicated is proper.

Thus, it would be unduly burdensome for the examiner to search all the claimed inventions being sought in the pending claims.

Applicant is advised that the reply for this requirement to be complete must include an election of the invention to be examined even though the requirement may be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Dowell whose telephone number is (571)272-5540. The examiner can normally be reached on M-F, 8-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram R. Shukla can be reached on (571)272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Anne-Marie Falk

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